

## REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claims 6 and 9 have been canceled without prejudice or disclaimer of the subject matter recited therein. Further, claims 1-5, 7, and 10-16 have been amended to further clarify Applicants' invention, and new claims 17-22 have been added. Support for amended claims 15-16 and new claims 18-20 can be found on pages 21-22 of the specification. No new matter has been added.

### **I. Rejections Under 35 U.S.C. § 112**

Claims 1-7, 9-11 and 13-16 have been rejected under 35 U.S.C. § 112, second paragraph. In order to expedite prosecution and not to acquiesce to the Examiner's rejections, applicants have amended the claims, thus rendering these rejections moot.

Accordingly, applicants respectfully request withdrawal of these rejections.

### **II. Rejections Under 35 U.S.C. § 103**

Claims 1, 4-7, 9, 10, 15 and 16 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Backensfeld et al. (U.S. Patent No. 798,338). Applicants respectfully traverse this rejection.

The claimed invention relates to, *inter alia*, complexes of a cyclodextrin ( $\beta$ - or  $\gamma$ -cyclodextrin) and a 14,17-C<sub>2</sub> bridged gestagen of formula I (see, for example, claim 1).

Backensfeld et al. relates to compositions for reducing oxidative degradation of 17- $\alpha$ -ethinylestradiol comprising cyclodextrin and estradiol. This reference does not disclose complexes of a 14,17-C<sub>2</sub> bridged gestagen and a cyclodextrin.

The Examiner has stated that the cited reference does not exemplify the use of a 14,17-C<sub>2</sub> bridged sterol, but that the reference suggests the use of these compounds at column 1, lines 40-45 of Backensfeld et al. Column 1, lines 40-45 discloses estrogens (not gestagens) to be used in the composition. Further, the gestagens that are mentioned at column 1, lines 47-49 of Backensfeld (i.e., norethisterone, levonorgestrel, gestodene, desorgestrel, and 3-ketodesorgestrel) do not possess a 14,17-C<sub>2</sub> bridge.

This is different from the claimed gestagens, which have a C2-bridge that extends to the C14-atom. Further, the claimed compounds have an  $\alpha$ -hydroxyketone side chain at the 17 position (see new claim 17)(The gestagens of Backensfeld et al. have a  $\beta$ -hydroxy group, an  $\alpha$ -hydrogen atom, or an  $\alpha$ -ethinyl group at position 17). This  $\alpha$ -hydroxy side chain gives rise to an acyloin rearrangement when the claimed gestagens are stored (see page 1, lines 20-23 of the specification). Thus, complexing the gestagen with cyclodextrin stabilizes the gestagen and prevents degradation of the gestagen via acyloin rearrangements. (The cited reference discloses reducing oxidative degradation of estradiols.)

Backensfeld et al. provides no teaching or suggestion to motivate the skilled artisan to stabilize gestagens with a 14,17-C<sub>2</sub> bridge or a 17-( $\alpha$ -hydroxyketone) side chain to prevent/reduce acyloin rearrangements of the gestagen. Further, the skilled artisan, upon reading Backensfeld et al., would not expect that a composition for reducing oxidative degradation comprising a cyclodextrin and an estradiol (or a gestagen with a 17- $\beta$ -hydroxy, a 17- $\alpha$ -hydrogen atom, or a 17- $\alpha$ -ethinyl group) would also stabilize a gestagen with a 14,17-C<sub>2</sub> bridge or a 17- $\alpha$ -hydroxyketone side chain to prevent/reduce degradation via acyloin rearrangements of the gestagen.

Accordingly, based on the foregoing, applicants respectfully request withdrawal of this rejection.

Claims 2, 3, 11, 13 and 14 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Backensfeld et al. (U.S. Patent No. 798,338) in view of Schollkopf et al. (WO 96/20209). Applicants respectfully traverse this rejection.

As discussed above, Backensfeld et al. does not rendered the claimed invention obvious, and Schollkopf et al. does not correct the deficiencies of Backensfeld. Therefore, these references, singly or in combination, do not render the claimed invention obvious.

Accordingly, applicants respectfully request withdrawal of this rejection.


In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

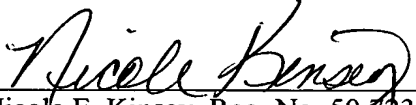
In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney or agent concerning such questions so that prosecution of this application may be expedited.

Appl. Serial No.: 09/807,402  
Attorney Docket No.: SCH-1808  
Reply Dated October 27, 2003  
Reply to Office Action of June 25, 2003

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
Anthony J. Zelano, Reg. No. 27,969  
Attorney for Applicant(s)

  
Nicole E. Kinsey, Reg. No. 50,723  
Agent for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Date: October 27, 2003

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I hereby certify that this correspondence is being deposited with the U.S. Postal Services as First Class Mail in an envelope addressed to: Commissioner of Patents, P O Box 1450, Alexandria, VA 22313-1450 on: October 27, 2003  
Name: Nicole Kinsey  
Signature: 